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EXAMINER	
DIXON, ANNETTE FREDRICKA	

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3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/686,268	**Applicant(s)** GOMEZ, ROY C.
	Examiner Annette F. Dixon	**Art Unit** 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-34* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In the amendment filed on September 14, 2006, Examiner acknowledges Claims 1-34 are pending in this application, with Claims 1, 18, and 19 having been amended.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1. Determining the scope and contents of the prior art.
   2. Ascertaining the differences between the prior art and the claims at issue.
   3. Resolving the level of ordinary skill in the pertinent art.
   4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-3, 5, 8, 12-20, 22, 25 and 29-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordewick et al. (6,418,928) in view of Sullivan (4,944,310).

4. **As to Claim 1,** Bordewick discloses a nasal mask assembly comprising a nasal cup (16) adapted to cover a patient's nose, said nasal cup having a perimeter (28), an internal cavity (the portion of the nasal cup 16 located inside the perimeter 28), an input port (38) having an internal end (the nasal prongs 14) within said internal cavity of said

nasal cup and an external end (22) external to said nasal cup, and a nasal delivery system (26) in fluid communication with said internal end of said input port and contained within said internal cavity, wherein said nasal delivery system comprises a pair of nasal prongs (14) in fluid communication with said internal end of said input port; a source tube (42) in fluid communication with said external end of said input port of said nasal cup and adapted to be in fluid communication with the fluid source such that the fluid is delivered from the fluid source to the patient's nostrils through said nasal prongs of said nasal delivery system; and a means for securing (the combination of elements 50, 51,52, and 53) said nasal cup over the patient's nose. (Figures 1-3). Yet Bordewick does not expressly disclose the nasal prongs to have an outer diameter less than the inner diameter of the patient's nostrils and extending into the patient's nostrils. However, at the time the invention was made the use of nasal prongs extending into the patient's nostrils was well known. Specifically, Sullivan teaches, and as well known in the art, nasal prongs (8) having the recited limitations for the purpose of enabling fluid to enter directly into the patient's nostrils (Column 2, Lines 36-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick to include the nasal prongs of Sullivan to provide a means for the fluid to enter directly into the patient's nostrils, thus enabling targeted delivery of fluid.

5. **As to Claim 2,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses the nasal mask assembly for use with a CPAP device for the

delivery of breathable gas or oxygen for patients suffering with sleep apnea. (Column 5, Lines 8-12).

6. **As to Claim 3,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a fastening mechanism connected to the nasal cup (the combination of elements 50, 51,52, and 53). (Figure 1 and Column 4, Lines 35-42).

7. **As to Claims 5 and 8,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claims 5 and 8,** with the exception of a molding means comprising a nasal cup made of a moldable material. However, the use of a moldable nasal cup was well known at the time the invention was made. Specifically, Sullivan teaches a moldable nasal cup (5) for the purpose of enabling the nasal cup to be firmly sealed to the patient's nose. (Column 1, Lines 48-50 and Column 2, Lines 30-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick to include the molding means of Sullivan for the purpose of providing additional comfort means and preventing the leakage of gas.

8. **As to Claim 12,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a delivery tube (26) in fluid communication with said internal end of said input port (38) and said nasal prongs (14). (Figures 1-3).

9. **As to Claim 13,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a delivery tube (26) that is generally horizontal and said internal end of said input port is about centrally attached to said delivery tube. Regarding the structural design of the delivery tube, the delivery tube (26) is more horizontal than

vertical and thus meets the limitations of the delivery tube being generally horizontal. Regarding the structural characteristics of the delivery tube, as seen in Figure 3, the delivery tube (26) is attached to the input port (38). Moreover, Applicant has not asserted the general shape of the delivery tube in a horizontal structure provides a particular advantage, solves a stated problem or serves a particular purpose, thus the use of a horizontal delivery tube lacks criticality in its design.

10. **As to Claim 14,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a delivery tube (26) having open ends (the out put of the nasal prongs 14) in fluid communication with said internal cavity of said nasal cup. Inherently, the nasal prongs perform the function of providing the fluid communication of the delivery tube gas to the internal cavity of the nasal cup.

11. **As to Claim 15,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a nasal cup (16) having a general shape of a human nose. (Figures 1-3). As well known, the general shape of a human nose is triangular. The mask of Bordewick is generally in a triangular shape and thus complies with the limitations. Moreover, Applicant has not asserted the general shape of the nasal cup provides a particular advantage, solves a stated problem or serves a particular purpose, thus the use of a horizontal delivery tube lacks criticality in its design.

12. **As to Claim 16,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claim 16,** but does not expressly disclose the nasal cup is made of a clear plastic. At the time the invention was made, clear nasal cups were well known for the purpose of

assisting the medical personnel in the proper placement of the nasal cup. Therefore, it would have been obvious to one having ordinary skill in the art to have a clear plastic nasal cup as the Applicant has done. Moreover Applicant has not asserted that the clear plastic nasal cup recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of assisting in the proper placement of the nasal mask assembly on the patient, thus the use of this clear plastic nasal cup lacks criticality in its design.

13. **As to Claim 17,** the system of Bordewick / Sullivan is discussed in Claim 1. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claim 17,** but does not expressly disclose the nasal prongs are at least about one inch in length. At the time the invention was made, various lengths of nasal prongs were well known. Therefore, it would have been obvious to one having ordinary skill in the art to disclose a specific length to the nasal prong as the Applicant has done. Moreover, Applicant has not asserted that the specific one (1) inch length of the nasal prong recited provides a particular advantage, solves a stated problem, or serves a purpose, thus the use of a specific one (1) inch length of the nasal prong lacks criticality in its design. Furthermore, depending on the patient (neonate, child, adult, or animal) using the nasal mask assembly device, the nasal prong length would be modified.

14. **As to Claim 18,** Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a nasal mask assembly comprising a nasal cup (16) adapted to cover a patient's nose, said nasal cup having a perimeter (28), an internal cavity (the portion of the nasal cup 16

located inside the perimeter 28), an input port (38) having an internal end (the nasal prongs 14) within said internal cavity of said nasal cup and an external end (22) external to said nasal cup, and a nasal delivery system (26) in fluid communication with said internal end of said input port and contained within said internal cavity, wherein said nasal delivery system comprises a pair of nasal prongs (14) in fluid communication with said internal end of said input port; a source tube (42) in fluid communication with said external end of said input port of said nasal cup and adapted to be in fluid communication with the fluid source such that the fluid is delivered from the fluid source to the patient's nostrils through said nasal prongs of said nasal delivery system; and a means for securing (the combination of elements 50, 51,52, and 53) said nasal cup over the patient's nose. (Figures 1-3). Yet Bordewick does not expressly disclose the nasal prongs to have an outer diameter less than the inner diameter of the patient's nostrils and extending into the patient's nostrils. However, at the time the invention was made the use of nasal prongs extending into the patient's nostrils was well known. Specifically, Sullivan teaches, and as well known in the art, nasal prongs (8) having the recited limitations for the purpose of enabling fluid to enter directly into the patient's nostrils (Column 2, Lines 36-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick to include the nasal prongs of Sullivan to provide a means for the fluid to enter directly into the patient's nostrils, thus enabling targeted delivery of fluid.

15. **As to Claim 19,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is

inherent in the use of the apparatus. Bordewick discloses the nasal mask assembly for use with a CPAP device for the delivery of breathable gas or oxygen for patients suffering with sleep apnea. (Column 5, Lines 8-12).

16. **As to Claim 20,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a fastening mechanism connected to the nasal cup (the combination of elements 50, 51,52, and 53). (Figure 1 and Column 4, Lines 35-42).

17. **As to Claims 22 and 25,** the system of Bordewick / Sullivan is discussed in Claim 18. The apparatus of Bordewick / Sullivan discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claims 22 and 25,** with the exception of a molding means comprising a nasal cup made of a moldable material. However, the use of a moldable nasal cup was well known at the time the invention was made. Specifically, Sullivan teaches a moldable nasal cup (5) for the purpose of enabling the nasal cup to be firmly sealed to the patient's nose. (Column 1, Lines 48-50 and Column 2, Lines 30-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick to include the molding means of Sullivan for the purpose of providing additional comfort means and preventing the leakage of gas.

18. **As to Claim 29,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is

inherent in the use of the apparatus. Bordewick discloses a delivery tube (26) in fluid communication with said internal end of said input port (38) and said nasal prongs (14). (Figures 1-3).

19. **As to Claim 30,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a delivery tube (26) that is generally horizontal and said internal end of said input port is about centrally attached to said delivery tube. Regarding the structural design of the delivery tube, the delivery tube (26) is more horizontal than vertical and thus meets the limitations of the delivery tube being generally horizontal. Regarding the structural characteristics of the delivery tube, as seen in Figure 3, the delivery tube (26) is attached to the input port (38). Moreover, Applicant has not asserted the general shape of the delivery tube in a horizontal structure provides a particular advantage, solves a stated problem or serves a particular purpose, thus the use of a horizontal delivery tube lacks criticality in its design.

20. **As to Claim 31,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a delivery tube (26) having open ends (the out put of the nasal prongs 14) in fluid communication with said internal cavity of said nasal cup. Inherently, the nasal prongs perform the function of providing the fluid communication of the delivery tube gas to the internal cavity of the nasal cup.

21. **As to Claim 32,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a nasal cup (16) having a general shape of a human nose. (Figures 1-3). As well known, the general shape of a human nose is triangular. The mask of Bordewick is generally in a triangular shape and thus complies with the limitations. Moreover, Applicant has not asserted the general shape of the nasal cup provides a particular advantage, solves a stated problem or serves a particular purpose, thus the use of a horizontal delivery tube lacks criticality in its design.

22. **As to Claim 33,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claim 33,** but does not expressly disclose the nasal cup is made of a clear plastic. At the time the invention was made, clear nasal cups were well known for the purpose of assisting the medical personnel in the proper placement of the nasal cup. Therefore, it would have been obvious to one having ordinary skill in the art to have a clear plastic nasal cup as the Applicant has done. Moreover Applicant has not asserted that the clear plastic nasal cup recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of assisting in the proper placement of the nasal mask assembly on the patient, thus the use of this clear plastic nasal cup lacks criticality in its design.

23. **As to Claim 34,** the system of Bordewick / Sullivan is discussed in Claim 18. Bordewick discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Bordewick discloses a nasal mask assembly comprising all the limitations recited in **Claim 34,** but does not expressly disclose the nasal prongs are at least about one inch in length. At the time the invention was made, various lengths of nasal prongs were well known. Therefore, it would have been obvious to one having ordinary skill in the art to disclose a specific length to the nasal prong as the Applicant has done. Moreover, Applicant has not asserted that the specific one (1) inch length of the nasal prong recited provides a particular advantage, solves a stated problem, or serves a purpose, thus the use of a specific one (1) inch length of the nasal prong lacks criticality in its design. Furthermore, depending on the patient (neonate, child, adult, or animal) using the nasal mask assembly device, the nasal prong length would be modified.

24. **Claims 4 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordewick et al. (6,418,928) in view of Sullivan (4,944,310) as applied to claims 3 and 20 above, and further in view of Belfer (5,918,598).

25. **As to Claim 4,** the system of Bordewick/Sullivan is discussed in Claim 3 and discloses a nasal mask assembly having a fastening mechanism (the combination of elements 50, 51,52, and 53) comprising all the limitations recited in **Claim 4,** with the exception of the adhesive along the interior of said perimeter of the nasal cup. However, the use of adhesive to attach a facemask to the patient was well known at the

time the invention was made. Specifically, Belfer teaches adhesive applied to the facemask for the purpose of insuring a better seal to the patient's face thus resulting in less gas leakage. (Column 4, Line 50 thru Column 5, Line 19 and Column 7, Lines 6-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick / Sullivan to include the adhesive of Belfer for the purpose of reducing potential gas leakage and creating another sealing means for the mask to be attached to the patient.

26. **As to Claim 21,** the apparatus of Bordewick /Sullivan, as discussed in claim 20, further modified by Belfer discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Please see the rejection of claim 4.

27. **Claims 6, 7, and 22-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordewick et al. (6,418,928) in view of Sullivan (4,944,310) as applied to claims 5 and 18, and further in view of Bartos (4,354,488).

28. **As to Claims 6 and 7,** the system of Bordewick / Sullivan is discussed in Claim 5 and discloses a nasal mask assembly comprising all the limitations recited in **Claims 6 and 7,** with exception of a molding means. However, the use of a molding means for a nasal cup was well known at the time the invention was made. Specifically, Bartos teaches a pliable aluminum clip (93) positioned along the perimeter of the nasal cup and made of metal that enables the patient to adjust the mask. (Column 11, Lines 56-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify the device of Bordewick / Sullivan to include the molding means of Bartos for the purpose of enabling the patient to adjust the placement of the mask thereby providing additional comfort means to the patient.

29. **As to Claim 22-24,** the apparatus of Bordewick / Sullivan, discussed in Claim 18, further modified by Bartos discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Please see the rejection of claims 6 and 7.

30. **Claims 9-11 and 26-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bordewick et al. (6,418,928) in view of Sullivan (4,944,310) as applied to claims 1 and 18, and further in view of Bohn et al. (6,860,268).

31. **As to Claims 9-11,** the system of Bordewick / Sullivan is discussed in Claim 1 and discloses a nasal mask assembly comprising all the limitations recited in **Claims 9-11,** with the exception of a rotation means with a pivotal import tube. However, the use of a rotation means in combination with a nasal cup was well known. Specifically Bohn teaches a swivel (24) that is freely rotatable around the port (23) to permit the movement of the tubing (22) without displacing the mask (20) from the patient's face. (Figures 1, 5b, and Column 6, Lines 47-54). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bordewick / Sullivan to include the rotation means of Bohn as taught to prevent the tubing (22) from reducing the visibility of the patient.

32. **As to Claims 26-28,** the apparatus of Bordewick / Sullivan, discussed in claim 18, further modified by Bohn discloses a nasal mask assembly apparatus wherein the recited method is inherent in the use of the apparatus. Please see the rejection of claims 9-11.

Response to Arguments

33. Applicant's arguments filed September 14, 2006 have been fully considered but they are not persuasive. Applicant's arguments are not commensurate with the scope of the claims. Applicant argues that the Bordewick prior art reference does not teach or fairly suggest the "nasal mask with nasal prongs that can *simultaneously* deliver breathable liquid from both the internal cavity of the nasal mask and the nasal prongs to the patient" (emphasis added). However, this assertion is not recited in Applicant's claims. Further, Applicant has amended the claims to include a structural characteristic that is well known in the art of nasal prongs. Nevertheless, as Applicant has not amended the claims to disclose Applicant's invention of a breathing system capable of delivering breathable gas from both the mask and the nasal prongs, the rejection of Claims 1-34 is deemed proper to satisfy the current claim limitations.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771
November 21, 2006

TEENA MITCHELL
PRIMARY EXAMINER